REMARKS

Claims 1-147 are currently pending in the application. Claims 28-66 and 101-139 are withdrawn. Claims 1, 6, 23, 26, 74, 79, 93, 96, and 99 are amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

The specification has been amended to delete the Abstract on page 976. The Abstract on page 201 is the correct Abstract.

Claim Objections

The Office Action states that claims 1-27, 67-100 and 140-147 are objected to, because the recitation "a second amino acid sequence comprising a ligand for a cell surface polypeptide" is allegedly awkward. Applicants have amended the claims consistent with the language suggested in the Office action.

In addition, the Office Action states that claims 1-27, and 67-73 are objected to for the recitation "a nucleic acid encoding." The claims have been amended to recite "a nucleic acid molecule encoding" consistent with the Examiner's suggestion.

Rejection of Claims 74-100 and 140-147 Under 35 U.S.C. §101

The Office Action states that claims 74-100 and 140-147 are rejected under §101 on the grounds that they are directed to non-statutory subject matter. Specifically, the Office Action states that these claims are directed to a "host cell comprising a nucleic acid molecule encoding a fusion polypeptide", and that the claims do not particularly point out any non-naturally differences between the claimed products and the naturally occurring products. Applicants disagree, and accordingly traverse the rejection.

All of the limitations set forth in the cited claims are essential to the embodiments claimed therein. In particular, these claims prescribe that the recited fusion polypeptide comprise first and second amino acid sequences, the characteristics of which are expressly limited.

Applicants are unaware of any evidence that any fusion polypeptide meeting the claim limitations, or any nucleic acid molecule encoding such a fusion polypeptide, exists in nature. Therefore, Applicants are unaware of any host cell that naturally comprises the recited nucleic acid molecule. Accordingly, in the absence of evidence to the contrary, any host cell falling under the scope of the cited claims must necessarily derive from the hand of man.

In view of the foregoing, Applicants respectfully request that the rejection be withdrawn.

Rejection of Claims 6-14, 23, and 26, 79-87, 93, 96, and 99 Under 35 U.S.C. §112, Second Paragraph

The Office Action states that claims 6-14, 23, and 26, 79-87, 96, and 99 are rejected for indefiniteness under 35 USC 112, second paragraph on the grounds that the recitation "at least about", particularly the word "about", renders the relevant claims indefinite. Applicants respectfully disagree. Nevertheless, in order to expedite prosecution, Applicants are herewith amending the claims to remove the word "about".

The Office Action also states that claim 93 is rejected for improper antecedent support. Applicants have amended claim 93 to properly depend from claim 91.

Rejection of Claims 23, 26, 96, and 99 Under 35 U.S.C. §112, First Paragraph

The Office Action states that claims 23, 26, 96, and 99 are rejected under 35 U.S.C. §112, first paragraph on the grounds that they allegedly fail to comply with the written description requirement. The Office Action states that the limitation that the second amino acid sequence comprise at least five contiguous amino acids of a naturally occurring GM-CSF is directed at a genus, and further states that Applicants fail to provide adequate written description of the genus by providing sufficient description of a representative number of species. Applicants traverse the rejection.

First, Applicants note that they were in full possession of the claimed invention at the time the application was filed. The species described fully embodies all elements of the invention as claimed, and the specification therefore clearly conveys possession of the claimed

invention to one skilled in the art. Applicants further note that the limitation regarding "at least five contiguous amino acids" is meant to exclude compositions failing to meet this standard, and that anyone reasonably skilled in the art could easily discern whether, on that basis, a given composition fell within or without the potential purview of the claims.

Applicants further note that there is extensive and well-known information in the literature regarding which amino acids of GM-CSF molecules are, respectively, necessary or dispensable for receptor binding and/or bioactivity. See, for example, Shanafelt et al., 1991, J. Biol. Chem. 266: 13804; Shanafelt and Kastelein, 1989, PNAS 86: 4872; Hercus et al., 1994, Blood 83:3500; Altman and Kastelein, 1995, J. Biol. Chem. 270: 2233; Monfardini et al., 1996, J. Biol. Chem. 271: 2966; Lopez et al., 1992 EMBO 11: 909; Meropol et al., 1992 J. Biol. Chem. 267: 14266; Schanafelt and Kastelein, 1992 J. Biol. Chem., 267: 25466; Seelig et al., 1994, J. Biol. Chem. 269: 5548; Shanafelt et al., 1991, EMBO 10: 4105 (Exhibits A-J, respectively). Thus, one skilled in the art would easily discern many members of a genus from the disclosures of the instant specification, and would recognize that the inventors were, correspondingly, in possession of many such members.

The Office Action acknowledges that adequate written description can rest on disclosure of relevant identifying characteristics, and sets forth a number of specific means by which this approach can be perfected. For example, the delineation of physical and/or chemical properties and functional characteristics can be sufficient to satisfy the written description requirement. Applicants agree that such criteria can fulfill the written description requirement. In fact, a key functional limitation is already present in the claims that derives from the description in the specification. That is, that the second amino acid sequence must be a ligand for a cell surface polypeptide chosen from the list iterated in claim 1. This clearly defines a genus to one skilled in the art, and indicates full possession of the claimed invention. To make this point clearer, Applicants have amended claims 23, 26, 96, and 99 to depend from claims 22, 25, 95, and 98, respectively.

Accordingly, Applicants respectfully request that Examiner withdraw the rejection.

Rejection of Claims 1-2, 4-8, 15-16, 18-21, 69-70, 72-75, 77-81, 88-89, 91-94, 142, 144, and 146 Under 35 U.S.C. §102

The Office Action states that claims 1-2, 4-8, 15-16, 18-21, 69-70, 72-75, 77-81, 88-89, 91-94, 142, 144, and 146 are rejected under §102 for lack of novelty over Ramshaw et al., U.S. Pat. No. 5,866,131. The Office Action states that Ramshaw et al. teaches a fusion polypeptide comprising a first amino acid sequence that can bind to a carbohydrate, and a second amino acid sequence that is a ligand for a cell surface polypeptide, particularly a cytokine receptor. The Office Action states further that the first amino acid sequence is the hemagglutinin protein, and that the second amino acid sequence includes the murine IL-2 protein, the murine TNF protein, and the murine IL-3 protein. Applicants respectfully traverse the rejection.

Ramshaw et al., in fact, does not teach a fusion polypeptide at all. Although this reference teaches nucleic acid constructs that encode multiple amino acid sequences, they are expressed as separate molecules, rather than as a fusion polypeptide. This is expressly evident from the drawings of Ramshaw et al, especially Figure 6a. Moreover, Ramshaw et al. clearly states at column 7, lines 6-8, that the hemagglutinin and cytokine were coexpressed from the viral constructs, "but from separate sites in the viral genome." Thus, they are not combined in a fusion polypeptide.

In order to support a rejection under 35 USC 102, a reference must teach all elements of the claimed invention. Since a fusion polypeptide is an essential element of the claimed invention, and since Ramshaw et al fails to teach a fusion polypeptide, the Ramshaw et al. does not anticipate the instant claims.

The Office Action also states that claim 71 is rejected as being anticipated by Ramshaw et al as evidenced by Wright et al, U.S. Pat. No. 6,949,695. Applicants traverse the rejection. The Office Action applies Ramshaw et al. as set forth above, and asserts that Wright et al. teaches that certain transcription control sequences can function in prokaryotic, yeast, and insect cells. As set forth hereinabove, however, Ramshaw et al. does not teach a fusion polypeptide. Therefore, any contribution from Wright et al. with respect to transcription control sequences is

irrelevant, because Ramshaw et al. fails to teach fusion polypeptides, even if considered in view of Wright et al.

Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejection of Claims 3, 9-14, 17, 22-27, 67-68, 76, 82-87, 90, 95-100, 140-141, 143, 145, and 147 Under 35 U.S.C. §103

The Office Action states that claim 3 and 76 are rejected under §103 as being obvious over Ramshaw et al, discussed above, in view of Meyers et al, U.S. Pat. No. 6,911,317. Applicants traverse the rejection.

As discussed above, Ramshaw et al. does not teach the fusion polypeptide recited in claim 1 or 74, and the rejected claims depend directly or indirectly from claims 1 and 74. There is no teaching in Meyers et al. to supplement the deficient teachings of Ramshaw et al. Accordingly, even if combined, the references cited to not teach each element of the clamed invention. Furthermore, given their widely disparate teachings, there would have been no motivation to combine these references, nor is it clear how they could be combined to yield the teachings of the instant invention.

The Office Action also states that claims 9-14 and 82-87 are rejected as being obvious over Ramshaw et al. in view of Fiers et al., U.S. PreGrant Pub No. 20030129197. Applicants traverse the rejection.

Again, as discussed above, Ramshaw et al. does not teach the fusion polypeptide recited in claim 1, 6-8, 74, or 79-81, and the rejected claims depend directly or indirectly from these claims. There is no teaching in Fiers et al. to supplement the deficient teachings of Ramshaw et al. Accordingly, even if combined, the references cited to not teach each element of the clamed invention.

The Office Action also states that claim 17 and 90 are rejected as being obvious over Ramshaw et al., that claims 22-27 and 95-100 are rejected as being obvious over Ramshaw et al.

in view of Wortham et al., that claims 67-68 and 140-141 are rejected as being obvious over Ramshaw et al. in view of Natesan, U.S. Pat. No. 6,015,709, and that claims 143, 145, and 147 are rejected as being obvious over Ramshaw et al. in view of Wright et al. Applicants traverse the rejections.

In each case, as above, Ramshaw et al. does not teach the fusion polypeptide recited in the claims from which the rejected claims directly or indirectly depend. There is no teaching in the secondary references to supplement the deficient teachings of Ramshaw et al. Accordingly, even if combined, the references cited to not teach each element of the clamed invention.

Accordingly, Applicants request that the rejections be reconsidered and withdrawn.

Double Patenting

The Office Action states that the instant claims are rejected under the judicially created doctrine of obviousness type double patenting in view of several co-pending applications. Upon notification of allowable subject matter in the instant case, Applicants will timely file a terminal disclaimer effective to obviate the double patenting rejection.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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